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Fact Sheet for the
Honorable Cardiss Collins
House of Representatives

December 1985

FOOD AND DRUG ADMINISTRATION

Interstate Milk Shippers Program

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ORIGINAL

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UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

December 20, 1985

HUMAN RESOURCES DIVISION
B-221473

The Honorable Cardiss Collins
House of Representatives

Dear Ms. Collins:

In response to your July 12, 1985, letter and later discussions with your office, we reviewed Food and Drug Administration (FDA) actions underway or planned as part of its Interstate Milk Shippers Program. FDA investigations of dairy plants, including the one in Illinois that recently distributed salmonella-contaminated milk, showed that greater emphasis needs to be placed on identifying and correcting weaknesses related to milk pasteurization. FDA has responsibility under the Public Health Service Act for assuring the safety of Grade A pasteurized milk.

We briefed your staff on the results of our work related to the questions you raised, and we agreed to provide written information addressing the following three questions.

--Are testing and inspection procedures and guidance in the milk safety program in harmony with revisions made since 1978 to requirements for pasteurizing milk to assure reasonable compliance?

--(1) Do tests exist for measuring levels of bacteria and chemical contaminants lower than currently allowed in the Pasteurized Milk Ordinance for pasteurized Grade A milk, (2) is it technically and economically feasible to produce milk with lower levels of contaminants, and (3) are any dairy plants currently producing pasteurized milk with lower levels of contaminants?

--When will FDA be reporting and taking corrective actions based on its program initiatives being implemented during fiscal year 1986 and when will FDA reinstate evaluations of state programs that have been postponed for fiscal year 1986?

In doing our work, we relied primarily on interviews with Milk Safety Branch officials in the National Center for Food Safety and Applied Nutrition in FDA's Washington, D.C., headquarters and a review of documents related to program requirements, procedures, and activities obtained from their administrative files.

In summary, we found that:

--Testing procedures appear to have kept pace with the Pasteurized Milk Ordinance revisions; however, according to FDA, additional inspection guidance is needed for bulk milk haulers.

--Testing methods exist for detecting and measuring coliform and other bacteria, but not phosphatase and antibiotics, at levels lower than the current Pasteurized Milk Ordinance standards. Technology does not currently exist to allow plants to consistently produce pasteurized milk at levels significantly lower than provided in the Ordinance.

--FDA has actions underway or planned in fiscal year 1986 to address problems in the milk industry, particularly weaknesses in dairy plants related to milk pasteurization. These measures are intended to help assure that milk production, processing, and distribution controls in the industry are sufficient to preclude future disease outbreaks, such as the recent one in Illinois. FDA plans to report on the status of its initiatives in December 1986. State program evaluations, which were postponed to place greater attention on addressing problems noted in dairy plants, will be reinstated in fiscal year 1987.

While we did not obtain official comments on this document from the Department of Health and Human Services, we discussed the information contained herein with FDA's headquarters program officials and considered their views in developing the document.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this fact sheet until 30 days from its issue date. At that time we will send copies to the Commissioner of FDA and other interested parties and make copies available to others on request.

Should you need additional information on the contents of this document, please call me on 275-6207.

Sincerely yours,

David P. Baine

David P. Baine
Associate Director

INTERSTATE MILK SHIPPERS PROGRAM

The Interstate Milk Shippers Program, administered by the Food and Drug Administration (FDA), is a voluntary federal-state program directed at safeguarding the public health by ensuring a safe and wholesome supply of Grade A pasteurized milk. This program evolved from early concerns for adequate public health protection due to a lack of uniform application of principles and procedures to ensure sanitation of milk produced in the late 19th and early 20th centuries.

The Public Health Service began a study of milk protection and processing in the United States in 1907. The cooperative efforts of the Service and the state of Alabama resulted in the publication of a proposed Standard Milk Ordinance in 1924. The Service called for state and local milk control agencies to voluntarily adopt the Ordinance. The states have responsibility for the routine enforcement of their state milk laws or regulations. As urbanization accelerated in the 1940's, however, concern grew for preventing contamination of highly perishable dairy products, particularly milk, shipped in interstate commerce.

To address this concern, the National Conference on Interstate Milk Shipments was formed in 1950. The Conference is composed of representatives from state and local regulatory agencies, the dairy industry, and FDA. Public Health Service responsibilities for administering this voluntary program were transferred to FDA in 1969. The Conference, which meets every 2 years, deliberates on the problems that affect sanitation requirements in the processing and distribution of milk and milk products. A formal agreement among the participating states (all 50 participate) is published in a document Procedures Governing the Cooperative State/Public Health Service/FDA Program for Certification of Interstate Milk Shippers.

The Conference's principal purpose is to discuss and vote on changes to the procedures governing the cooperative milk program and changes to the Grade A Pasteurized Milk Ordinance.[1] The Conference's only voting delegates are representatives of state regulatory agencies. Industry and FDA representatives do not vote on changes to the Ordinance. However, the Ordinance is written and published by FDA as a recommended uniform ordinance for all participating state or local regulatory agencies to adopt as their state or local milk sanitation requirements.

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[1]Before 1965, called the 1924 Standard Milk Ordinance.

The Milk Safety Branch in FDA's National Center for Food Safety and Applied Nutrition in Washington, D.C., has the primary responsibility for directing FDA's activities under the program. FDA's 10 regional offices handle the day-to-day interaction with the states' programs. FDA's responsibilities under the Interstate Milk Shippers Program include inspecting[2] dairy plants, evaluating the adequacy of state milk programs, assuring that FDA regional milk specialists and state milk-rating officers correctly interpret and apply sanitation standards and procedures relevant to the program, publishing a quarterly list of milk shippers approved for interstate commerce, assisting in training and sponsoring seminars, and evaluating and approving state laboratory facilities and procedures.

FDA's compliance program guidance manual for the milk safety program requires FDA regional milk specialists to identify and track public health problems and state control program needs from year to year to determine the status of public health protection, to identify trends in state controls over time, and to help assess the relative impact of FDA program activities on promoting public health. This information is derived principally from FDA's evaluations of state milk programs.

The information we obtained concerning selected activities involving the Interstate Milk Shippers Program follows.

HAVE TESTING AND INSPECTION PROCEDURES KEPT PACE WITH THE ORDINANCE REVISIONS MADE SINCE 1978?

According to FDA officials, the Pasteurized Milk Ordinance contains up-to-date test procedures and testing apparatus specifications for testing pasteurization equipment and controls and testing methods for determining the presence of coliform[3]

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[2]These inspections form the basis for FDA to determine whether states' approval of milk plants for shipping Grade A pasteurized milk in interstate commerce are valid. States are responsible for taking regulatory action that may be necessary based on these inspection results.

[3]A form of bacteria. Its existence above the permissible level indicates the presence of pathogens (disease-causing bacteria, such as salmonella).

and other bacteria, phosphatase,[4] and antibiotics in pasteurized milk. Moreover, they believe inspection procedures have kept pace with changes to the Ordinance. They said many changes have been made to the Ordinance since 1924 to keep it current with improved testing and inspection methods resulting from technological advances. Since 1978, changes specifically affecting testing and inspections were made in 1980 and 1982, respectively.

In July 1980 a new test method was incorporated in the Ordinance for detecting the presence and levels of antibiotics remaining in pasteurized milk. In January 1982 a maximum level of antibiotics permissible in milk was established in the Ordinance using the 1980 method. FDA headquarters officials told us this method is the most current available for testing for antibiotics in milk.

Also in January 1982, revisions were made to the Ordinance requiring the inspection of bulk milk haulers' pickup and sampling procedures at least every 24 months.

In carrying out its responsibility under the program, FDA evaluates its regional milk specialists and state milk-rating officers by requiring them to demonstrate their ability to conduct inspections based on preprinted inspection reports included in appendix M of the Ordinance. The inspectors and specialists must show their knowledge and understanding of the Ordinance and implementing policies and procedures in completing these inspection reports.

FDA's inspector operations manual contains the requirements for FDA's evaluation of its regional milk specialists' and state milk-rating officers' ability to carry out their responsibilities. We noted that the manual has not been updated to incorporate revisions made to the Ordinance pertaining to the ability of rating officers and specialists to inspect bulk milk haulers' pickup and sampling procedures. Moreover, the preprinted inspection reports contained in the Ordinance have not been updated to reflect the 1982 inspection revision. FDA officials stated that step-by-step inspection procedures have not been consolidated in any one FDA document for the milk safety program. They believed that a review of all the federal documents pertaining to the program would provide a clear indication of

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[4]An enzyme or a catalyst always present in raw milk that causes biochemical reactions in living organisms. Phosphatase itself would not be harmful to public health, but the test for it serves as an indicator of improper pasteurization.

the steps necessary for inspecting the dairy farms, holding tanks for receiving and transferring raw milk, and milk plants. According to these officials, more complete inspection guidance for bulk milk haulers is needed; for example, the Ordinance should be expanded to include requirements covering bulk hauler practices and to establish a specific bulk milk hauler enforcement program. The officials indicated that a committee has been established as part of the National Conference on Interstate Milk Shipment's activities to develop specific recommendations in this regard.

The FDA officials also told us the states have inspection operations manuals that serve as guidelines for their state milk-rating officers. However, they did not have information indicating the adequacy of the states' guidance for inspecting and testing dairy farms, bulk milk haulers' pickup tankers, receiving and transfer stations, and milk plants.

IS IT TECHNICALLY AND ECONOMICALLY FEASIBLE TO PRODUCE MILK WITH BACTERIA AND CHEMICAL CONTAMINANTS AT LEVELS LOWER THAN PROVIDED IN THE ORDINANCE?

The Ordinance provides standards for the maximum levels of bacteria, coliform, phosphatase, and antibiotics that can remain in Grade A milk after pasteurization. FDA officials responsible for the milk safety program informed us that testing methodologies for bacteria and coliform contamination exist for detecting and measuring levels lower than those provided for in the current Ordinance and that many milk plants produce milk at levels lower than the Ordinance standards. However, they pointed out that plants' ability to produce milk at such levels varies greatly depending on such factors as the level of bacteria in raw milk produced by the dairy farm and their ability to eliminate the bacteria through pasteurization.

The FDA officials believe that even though testing methods identify the lower levels of bacteria and coliform achieved, present technology does not allow plants to consistently produce pasteurized milk at levels significantly lower than provided in the Ordinance. Moreover, they told us that there is no scientific evidence showing that a lower level of these substances would significantly reduce the health risk to consumers. One official indicated, however, that it would be advantageous for milk-producing plants to strive to lower bacteria and coliform levels to extend the shelf life (currently about 10 days) of pasteurized milk.

FDA officials told us that tests do not exist for measuring phosphatase and antibiotics at levels lower than provided for in

the Ordinance. In addition, they indicated that it is not now technically feasible to produce milk containing lower levels of these substances than provided for in the Ordinance.

WHEN WILL FDA'S PLANNED INITIATIVES BE REPORTED AND RESULTS ACTED ON AND STATE PROGRAM EVALUATIONS REINSTATED?

Over the past few years, pasteurized milk containing disease-causing microorganisms has caused human illnesses. According to FDA, these microorganisms may be occurring with greater frequency in milk and therefore may affect more people. Investigations of dairy plants, including the one in Illinois that distributed salmonella-contaminated milk in April 1985, showed that milk may become contaminated from such factors as deficient systems and equipment for pasteurizing milk and inadequate controls to safeguard milk after pasteurization.

To address these concerns and help assure there are no major systemic weaknesses in the milk industry that could cause disease outbreaks, FDA has underway or plans to implement several initiatives in fiscal year 1986. These include (1) emphasizing more comprehensive dairy plant inspections, (2) establishing a microbiological surveillance program to detect pathogenic contamination of finished products, (3) tabulating and analyzing FDA dairy plant inspections and preparing a national report on the results, and (4) intensifying and upgrading training and evaluation of FDA milk specialists and state milk-rating officers.

According to FDA officials, more in-depth dairy plant inspections are the principal focus of the 1986 initiatives. The initiatives call for inspecting--over the next 2 to 3 years--all dairy plants operating in interstate commerce. Increased emphasis will be placed on (1) thoroughly reviewing milk plants when they are not in operation, (2) thoroughly reviewing plant production records, (3) comprehensively reviewing the design and placement of piping for milk in the plants including cross-connections, (4) closely evaluating manufacturing critical control points where milk could become contaminated in the plants and devices in the plants used for detecting possible postpasteurization contamination of milk, and (5) comprehensively testing and evaluating the plants' pasteurizing equipment.

FDA has drafted a compliance program guidance manual for its regional offices to use in implementing the initiatives starting April 1, 1986. A report on the dairy plant inspections and other areas of emphasis undertaken is expected to be

published in December 1986. An FDA official told us problems identified based on its initiatives will be immediately corrected if possible. Some problems, however, may require extensive planning efforts, including the development of implementing policies and procedures.

According to an FDA official, evaluations of state programs have been postponed for fiscal year 1986 in order to focus on addressing problems noted in dairy plants. FDA plans to reinstate the state program evaluations in fiscal year 1987. The official said that FDA's other responsibilities and levels of activity under the Interstate Milk Shippers Program would remain about the same.

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